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Root Cause Analysis of Adverse Outcomes in the Obstetrics & Gynaecology: A Prospective Study at a Tertiary Care Centre

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ABSTRACT

Background: Adverse events are an unwanted outcome in the routine course of patient management, with an adverse event in Obstetrics assuming even greater importance because of the extended implications for the newborn. There is limited data available on the adverse event emanating from Obstetrics and Gynaecology care in Indian population. **Materials and Methods:** This prospective observational study which included all the consecutive inpatients admitted with the department of Obstetrics and Gynaecology over a period of 15 months at a tertiary care centre. Incidence of adverse events were noted. Root cause analysis of the events was done and contributory factors brought out were addressed. **Results:** The incidence of the adverse events in our study was 2.57 % (n=90) in a total of 3503 consecutive inpatients. The most common adverse event noted in our study was surgical site infection followed by birth asphyxia. The average duration of detection of adverse event was 8.5 days, with adverse event detected in 73% patients during admission. Out of these, 98.48% had a prolonged hospital stay which averaged 5.5 days. 58% of the adverse events were grade 3 in severity while 91.1% were deemed preventable. **Conclusion:** Adverse events carry a giant burden with them, but their incidence can definitely be cut down by adhering to institutional protocols, checklists, increased awareness and involvement at multiple levels of hierarchy.

KEYWORDS: Adverse Events, Observational Study, Root Cause Analysis, Surgical Site Infection, Patient Safety

INTRODUCTION

An adverse event is an undesirable occurrence following medical or surgical intervention in a patient, which may vary from a trivial discomfort to hospitalization, disability, life-threatening indisposition or death. This adverse event can occur at any time during treatment or after its cessation and may not have a causal relationship with the medical condition. [1, 2]

Healthcare systems in each country have safety programs with reporting system in place for monitoring adverse events. In India, programmes such as Materio-vigilance programme coordinated by Indian Pharmacopoeia Commission and Pharmacovigilance Programme of India are in place to monitor and control adverse events. In addition, recommendations from the WHO and societies in each discipline of medicine also exist. [3, 4]

Some adverse events are preventable, some predictable but unpreventable while some are unpredictable such as idiosyncratic drugs interactions. Adverse events in Obstetrics assume greater importance with implication not only for the patient but also for the foetus, compounding and multiplying the uncertainty and the risk of harm. Similarly, Gynaecology combines the risks of both medical and surgical specialties. [5]

There have been few studies reporting the incidence of adverse events in Obstetrics and Gynaecology, most being retrospective in nature with very few studies based on Indian population. The aim of this prospective study was to study the incidence of adverse events, emanating during Obstetrics and Gynaecology care in Indian population and to investigate and enumerate the contributing factors, enlisting the remedial measures taken for the same.

METHODS

This was a prospective observational study conducted at a tertiary care hospital in the Department of Obstetrics and Gynaecology over a period of 15 Months from Nov 2019 to Jan 2021.

Inclusion and Exclusion Criteria: All patients admitted to the Obstetrics and Gynaecology department during the

study period were eligible for inclusion. There were no exclusion criteria to ensure a comprehensive evaluation of adverse events across all inpatient cases.

The study was conducted in accordance with the ethical standards established in the Declaration of Helsinki. Informed written consent was taken from all the participants of the study. During the course of treatment in the hospital, any adverse event which developed was recorded and investigated.

Definition of Adverse Events: An adverse event was defined as any unfavourable and unintended outcome linked with the use of a medical/surgical treatment or procedure, with or without direct relation with the treatment/procedure. [6] Adverse events were recorded on a proforma for analysis which included patient details, details with respect to the medical or surgical condition of the patient, procedure and treatment details and details of the medical staff involved in the management of the case.

All adverse events were reported to the Hospital patient safety committee on these proformas which did the **Root Cause Analysis (RCA)** to analyse the probable contributory factors and to bring out the deficiencies if any. Each RCA was initiated within 72 hours of the event and completed within 45 days of initiation. The RCA team consisted of 4–6 people with interdisciplinary expertise, without any conflict of interest with the case under study. [7–9] Contributory Factors analysis was done based on contributory factor classification framework published by National Patient Safety Agency (NPSA), summarized in Table 1 . [10]

Grading of Adverse Events: Adverse events were graded from Grade I to grade V as per the Common Terminology Criteria for Adverse Events (CTCAE) version 5. [6]

Statistical Analysis

Data analysis was performed using STATA 11.2 (College Station, TX, USA) and Microsoft Excel (2018). The age distribution of study participants was expressed as mean ± standard deviation (SD). Pearson's chi-square test was used to assess the relationship between age groups and the presence of adverse events. The incidence and contributing factors of adverse events were expressed as frequencies and percentages. A p-value <0.05 was considered statistically significant.

RESULTS

Study Population: A total of 3,503 consecutive inpatients admitted to the Department of Obstetrics and Gynaecology were included in the study. Of these, 2,758 (78.73%) were obstetric cases, and 745 (21.27%) were non-obstetric cases, including both surgical and non-surgical admissions.

Incidence of Adverse Events: The overall incidence of adverse events was 2.57% (n=90). Among these, 74 (82.2%) were observed in obstetric cases, while 16 (17.8%) occurred in non-obstetric cases. The most common adverse events in obstetric cases were birth asphyxia requiring neonatal ICU admission (n=11, 0.40%) undiagnosed IUGR(0.36%) and surgical site infections (SSI) (0.33%). Notable adverse events included two cases of maternal mortality and six cases of neonatal mortality. Neonatal deaths were primarily due to birth asphyxia and undiagnosed congenital malformations. Surgical site infections (SSIs) were observed in 13 cases (0.4%) across both obstetric and non-obstetric cases. Additionally, there were two cases of retained foreign bodies, where surgical swabs were left in the vaginal cavity—one following an episiotomy and the other after a vaginal hysterectomy. The various adverse outcomes with their frequency in obstetric and non-obstetric cases are listed in Table 2 and Table 3 respectively.

Factors	Components
Patient factors	Clinical condition, Physical state of the patient, Social factors, Psychological factors, Interpersonal relationships
Staff factors	Physical issues, psychological issues, Social/Domestic issues, Personality issues, Cognitive factors
Treatment/Procedural factors	Guidelines, availability, knowledge and adherence of policies and procedures, access to Decision making aids, adequacy of procedural or task design
Communication factors	Adequacy and correctness of Verbal and written communication, Communication management
Equipment factors	Display, Reliability, Positioning, Usability, Safety
Working environment factors	Administrative support and infrastructure, Physical environment, Staffing ratio, Workload
Organizational factors	Conduciveness with organisational goals, Impact of policies/guidelines
Training factors	Adequacy of knowledge/experience, Adequacy of supervision, Availability of training aids/continuing medical education
Team factors	Role congruence, Effectiveness of leadership

Table 1: Contributory factor classification framework published by National Patient Safety Agency (NPSA) used for contributory factor analysis

Demographics and Adverse Events: The mean age of participants was 30.14 ± 4.21 years, ranging from 15 to 79 years. Maximum subjects were in the age group 26-35 years (n = 1366, 39%) and only seven subjects in the age group of >75. Patients with adverse events had a slightly lower

Adverse event	No.	Percent
Admission to Neonatal ICU for birth asphyxia	11	0.40%
Undiagnosed IUGR in booked patient	10	0.36%
Surgical site infection	9	0.33%
Neonatal mortality	6	0.22%
Birth trauma (Maternal + Foetal)	5	0.18%
Eclampsia	4	0.15%
Undiagnosed congenital malformation	3	0.11%
Intrauterine fetal demise	3	0.11%
Secondary PPH	3	0.11%
Shoulder dystocia	2	0.07%
Maternal death	2	0.07%
Manual Removal of Placenta	2	0.07%
Undiagnosed discrepancy in weight of twins in booked patient	2	0.07%
Medication error	2	0.07%
Injection site abscess	2	0.07%
Undiagnosed Placenta previa	1	0.04%
Neonatal convulsions	1	0.04%
Inadvertent visceral injury	1	0.04%
Neonatal hypothermia	1	0.04%
Urosepsis	1	0.04%
Undiagnosed breech presentation	1	0.04%
Incomplete Dilatation and Curettage	1	0.04%
Retained foreign body	1	0.04%

Table 2: Frequency of adverse events encountered during the study period in Obstetric cases (n=2758)

mean age of 28.88 ± 8.72 years. The highest incidence of adverse events (3.0%) was observed in the 26–35-year age group. However, a chi-square test for linear trend did not show a statistically significant relationship between age and the presence of adverse events (p=0.1763). Age distribution and adverse event incidence by age group are summarized inTable 4 .

Timing and Duration of Adverse Events: The average duration for detecting adverse events was 8.5 days post-causative event. Most adverse events (73.3%; n=66) were identified during hospital admission, while 26.7% (n=24) were detected after discharge, necessitating readmission in 14 cases. Among inpatients with adverse events, 98.48% experienced prolonged hospital stays, with an average extension of 5.5 days (range: 1–20 days). The longest hospital stay (30 days) occurred in a case of inadvertent ureteric injury during surgery. Out of the 90 subjects with adverse events, specific intervention to manage the adverse event was required in 79 subjects (87.78%).

Adverse event	No.	Percent
Surgical Site Infection	4	0.54%
Pressure Sore	2	0.27%
Documentation Errors	2	0.27%
Inadvertent visceral injury	2	0.27%
Inadvertent fall during hospital stay	2	0.27%
Retained foreign body	1	0.13%
Failed sterilisation	1	0.13%
Medication error	1	0.13%
Superficial Thrombophlebitis	1	0.13%

Table 3: Frequency of adverse events in Non-obstetric cases (n=745)

Age (years)	No.	Percent	No. with adverse events	Incidence
15-25	1352	38.60%	36	2.66%
26-35	1366	39.00%	41	3.00%
36-45	345	9.85%	6	1.74%
46-55	310	8.85%	5	1.61%
56-65	91	2.60%	1	1.10%
65-75	32	0.91%	1	3.13%
>75	7	0.20%	0	0.00%

Table 4: Age wise distribution of subjects and adverse events

Severity and Preventability: Adverse events were graded based on CTCAE criteria. Most were classified as Grade 3 (58%; n=52), indicating moderate severity. Grade 5 events (death) accounted for 12% (n=11) of cases. Severity distribution is detailed inTable 5.

Root Cause Analysis (RCA) revealed that 91.1% (n=82) of adverse events were deemed preventable. The most frequently identified contributory factors were training deficits and staff-related issues, followed by treatment/procedural factors and patient factors. Multiple contributory factors were identified in 72.2% (n=65) of cases. illustrates the frequency of these factors.

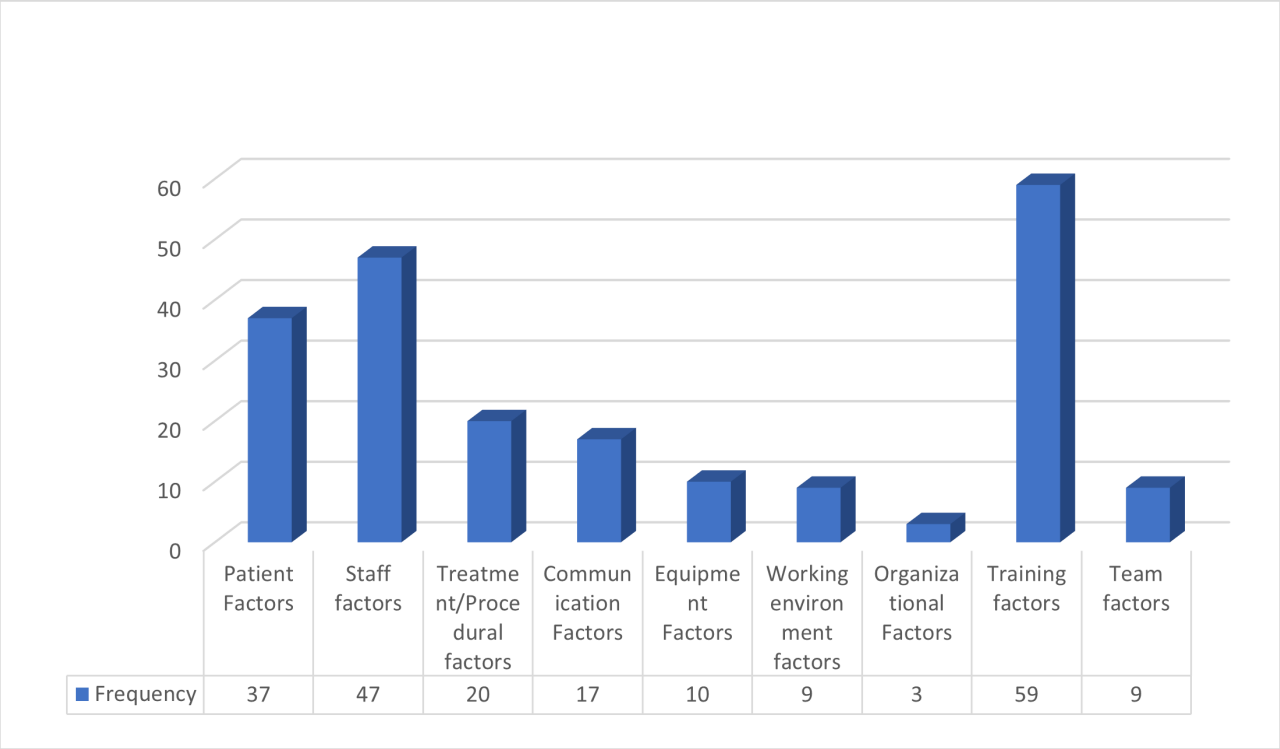

Figure 1: Frequency of contributory factors of adverse events asper Root cause analysis

Severity grade	Frequency	Percentage
Grade 1	12	13%
Grade 2	13	14%
Grade 3	52	58%
Grade 4	2	2%
Grade 5	11	12%

Table 5: Breakdown of adverse events (n=90) into severity grades as per the Common terminology criteria for adverse events (CTCAE)

DISCUSSION

Prevention of adverse events in management of patients has always been a matter of discussion, with many policies and guidelines in vogue to reduce their incidence. Studies have been done as early as in 1984, namely the Harvard Medical Practice study which reviewed 30,121 patient records and determined an adverse event rate of 3.7% out of which 27.6% were due to negligence. [11] The need of increasing patient's safety and prevention of adverse events in healthcare has also been advocated by the World Health Organization (WHO), with World Alliance for Patient Safety. [12] NHS Litigation Authority data of 2014-15 suggested that 10% of all negligence claims and 41 % of all the negligence payments were related to obstetric cases. [13]

Adverse outcomes are an undesirable reality affecting the patients and their families, health care providers and health care institutions. It has been advocated to disclose and discuss about adverse events with patients and their families. Studies and surveys also show that disclosure of an adverse event is expected by the patient along with an honest acknowledgement of responsibility, reducing the likelihood of litigation. The success of such disclosure programs is well documented. [14, 15] The primal impediments which health care providers face in disclosing the adverse events to patients include fear of complaints and litigations with future threat to reputation and job. Hence, health care facilities are recommended to follow a nonpunitive approach in this regard except for gross or repeated violations. [16]

In our study, the overall incidence of adverse events was 2.57 %, while that reported in previous similar studies, ranges from 0.3% - 23%. [17–21] The 2015 JOGC report also mentioned that the prevalence of AEs in the Obstetrics department was about 10%. [1] 82.2 % (n=74) of the adverse events were in the obstetric cases and even in the non-obstetric cases, 50 % (n=8) were in the surgical cases, which was similar to those reported in previous similar studies. [22] Correlation with age was significant with decrease in the incidence of adverse events with advancing age, a finding not found reported previously on literature research.

In our study, there were two cases of maternal mortality and six cases of neonatal mortality. The incidence of SSI in obstetric and non-obstetric surgical cases combined was

found to be in 13 cases (0.4 %). There were three cases of ureteric injury detected post operatively. In our study, there were two cases of retained foreign bodies, each with a swab left in vagina, one during episiotomy and one during vaginal hysterectomy.

Root cause analysis (RCA), a retrospective structured investigation was carried out for the adverse events to determine the fundamental or initiating factor leading to it. RCA identified that 91.1% (n=82) of the adverse events were preventable, more than what has been reported previously [18, 19], implying that effective interventions can undeniably improve the outcome. 87.78% (n=79) of the patients with adverse events required prolonged admission to hospital or were readmitted, implying the increased financial implication to the patients and the hospital with additional burden on the health care system. More than one contributory factor was identified in our study in 72.2 % of the cases, as reported previously [23], suggesting lapses at multiple levels.

Recommendations of RCA were put into action by the department. Few notable ones include creating a predefined team structure in labour room as also described in literature [24] and encouraging the team leader and the hospital administration to create an atmosphere of open communication and non-punitive approach to prevent health care workers involved from becoming second victims. All the administrative personnel maintaining Medical Records were made accountable for lapse at their level. Double checking of the documentation before any procedure, by the healthcare team was implemented. Other recommendations included strict adherence to the Institutional protocols and checklists, continuing medical education programme for the health care staff, obligatory discussion with the patients to address their concerns, debriefings for discussion after major procedures/surgeries. Overall, a non-punitive approach was followed except for gross or repeated violations. Dictum of 'who', 'what', 'when', 'where' and 'how' was strictly adhered to in clinical practice. Many of the above recommendations given have already been documented to be constructive in clinical practice. [25, 26] Knowledge generated was shared with other departments to enable organization wide learning and improvement.

There is need felt for conducting multi-centric study for validation of the recommendations to see if they do lead to reduced incidence of the adverse events. It would also be worthwhile to develop one common system of reporting in place, to ensure that maximum adverse events are reported without going unnoticed, which may have been a limitation of our study.

CONCLUSION

Adverse events are a major financial and psychological burden on the patient and the health care system. Identification of causative factors with the use of a multidisciplinary approach is required to reduce the incidence of adverse events. At the same time, supporting the patient and the healthcare workers involved is an administrative challenge requiring empathetic touch. However concomitantly, it must be emphasized that largely, it is the responsibility of the health care workers to recognize, predict, prevent and analyse the adverse events to reduce morbidity and mortality.

REFERENCES

1. Murray-Davis B, Mcdonald H, Cross-Sudworth F, Ahmed R, Simioni J, Dore S et al. Learning from Adverse Events in Obstetrics: Is a Standardized Computer Tool an Effective Strategy for Root Cause Analysis? J Obstet Gynaecol Can. 2015;37(8):728–735. doi:10.1016/S1701-2163(15)30178-X.
2. Raj-Kietla A, Kryska S, Horák S, SteM, Kulpok-Bagiński T, Ładny JR et al. Analysis of adverse events concerning gynecological and obstetric patients. GinPolMedProject. 2018;1(47):16–24. Available from: https://www.ginekologiaipoloznictwo.com/articles/analysis-of-adverse-events-concerning-gynecological-and-obstetric-patients.pdf.
3. Suke SG, Kosta P, Negi H. Role of Pharmacovigilance in India: An overview. Online J Public Health Inform. 2015;7(2):223–223.
4. Prakash J, Sachdeva R, Shrivastava TP, Jayachandran CV, Sahu A. Adverse event reporting tools and regulatory measures in India through outcome of Pharmacovigilance Programme of India. Indian J Pharmacol. 2021;53:143–52.
5. Matsaseng T, Moodley J. Adverse events in Gynecology at King Edward VIII Hospital. J Obstet Gynaecol. 2005;25(7):676–680.
6. U S Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE): Versian 5.0; 2017. Available from: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcae_v5_quick_reference_5x7.pdf.
7. National Patient Safety Foundation; Boston, MA. National Patient Safety Foundation. RCA2: Improving Root Cause Analyses and Actions to Prevent Harm; 2015. Available from: https://www.ihi.org/resources/tools/rca2-improving-root-cause-analyses-and-actions-prevent-harm.
8. Pettker CM. Systematic approaches to adverse events in obstetrics, Part II: Event analysis and response. Semin Perinatol. 2017;41(3).
9. Lusk C, Catchpole K. Teamwork and Trust for Patient Safety. In: Agrawal A, Bhatt J, editors. Patient Safety: A Case-based Innovative Playbook for Safer Care. Cham: Springer International Publishing; 2023. p. 89–99. doi:10.1007/978-3-031-35933-0$_7$.

10. National Perinatal Epidemiology Unit, Oxford, UK. National Patient Safety Agency: Root Cause Analysis Investigation tools - Contributory Factors Classification Framework; 2009. Available from: https://www.npeu.ox.ac.uk/assets/downloads/pmrt/3_Contributory%20Factors%20Classification%20Framework.pdf.

11. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991;324(6):370–376.

12. Edwards R, I. The WHO World Alliance for Patient Safety: a new challenge or an old one neglected? Drug Saf. 2005;28(5):379–86.

13. NHS Litigation Authority, London. Annual Review: Reports and Accounts 2014/15; 2015. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/454320/NHS_LA_Annual_Report_and_Accounts_2014-15.pdf.

14. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. JAMA. 2003;289(8):1001–1008.

15. Fowler FJ, Epstein A, Weingart SN, Annas CL, Bolcic-Jankovic D, Clarridge B. Adverse events during hospitalization: results of a patient survey. Jt Comm J Qual Patient Saf. 2008;34(10):34073–34075.

16. Scott SD, Hirschinger LE, Cox KR, Mccoig M, Brandt J, Hall LW. The natural history of recovery for the healthcare provider "second victim" after adverse patient events. Qual Saf Health Care. 2009;18(5):325–355. doi:doi: 10.1136/qshc.2009.032870.

17. November M, Chie L, Weingart SN, Henriksen K, Battles JB, Keyes MA. Physician-Reported Adverse Events and Medical Errors in Obstetrics and Gynecology. In: Advances in Patient Safety: New Directions and Alternative Approaches. vol. 1; 2008. .

18. Florea A, Caughey SS, Westland J, Berckmans M, Kennelly C, Beach C. The Ottawa hospital quality incident notification system for capturing adverse events in obstetrics. J Obstet Gynaecol Can. 2010;32(7):34569–34577.

19. Skoogh A, Hall-Lord ML, Bååth C, Bojö AS. Adverse events in women giving birth in a labor ward: a retrospective record review study. BMC Health Serv Res. 2021;21(1):1093–1093.

20. Forster AJ, Fung I, Caughey S, Oppenheimer L, Beach C, Shojania KG et al. Adverse events detected by clinical surveillance on an obstetric service. Obstet Gynecol. 2006;108(5):1073–83.

21. Pettker CM, Thung SF, Norwitz ER, Buhimschi CS, Raab CA, Copel JA. Impact of a comprehensive patient safety strategy on obstetric adverse events. Am J Obstet Gynecol. 0200;(5):492–493.

22. Otchi EH, Esena RK, Srofenyoh EK. Types and prevalence of adverse events among obstetric clients hospitalized in a secondary healthcare facility in Ghana. Journal of Patient Safety and Risk Management. 2019;24(6):238–244.

23. White AA, Pichert JW, Bledsoe SH, Irwin C, Entman SS. Cause and effect analysis of closed claims in obstetrics and gynecology. Obstet Gynecol. 2005;105(5):1031–1039.

24. Nielsen PE, Goldman MB, Mann S, Shapiro DE, Marcus RG, Pratt SD et al. Effects of teamwork training on adverse outcomes and process of care in labor and delivery: a randomized controlled trial. Obstet Gynecol. 2007;109(1):48–55.

25. Weiss PM, Miranda F. Transparency, apology and disclosure of adverse outcomes. Obstet Gynecol Clin North Am. 2008;35(1):53–62.

26. Margulies SL, Benham J, Liebermann J, Amdur R, Gaba N, Keller J. Adverse Events in Obstetrics: Impacts on Providers and Staff of Maternity Care. Cureus. 2020;12(1):e6732. doi:doi: 10.7759/cureus.6732.

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